

# UNITED STATES DEPARTMENT OF COMMERCE **United States Patent and Trademark Office**

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APPLICATION NO. FILING DATE		FILING DATE	FIRST NAMED INVENTOR		ATTO	ATTORNEY DOCKET NO.	
<u> </u>	09/526,8	55 03/17/	00 KIM		1-1	15280W003000	
_	020350 HM12/0606 TOWNSEND AND CREW TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO CA 94111-3834				EXAMINER		
1					BADIO, I	3	
•					ART UNIT	PAPER NUMBER	
					1616	10	
			·		DATE MALED:	06/06/01 .	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

PTO-90C (Rev. 11/00) 1- File Copy

	Application No.	Applicant(s)						
Office Action Summary	09/526,855	KIM ET AL.						
	Examiner	Art Unit						
	Barbara P Badio, Ph.D.	1616						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status								
1) Responsive to communication(s) filed on	<u> </u>							
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Thi	s action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposition of Claims								
4) Claim(s) 1-60 is/are pending in the application.								
4a) Of the above claim(s) 4.9-23.26-48 and 50-60 is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.								
6) Claim(s) <u>1-3,5-8,24,25 and 49</u> is/are rejected.	6)  Claim(s) <u>1-3,5-8,24,25 and 49</u> is/are rejected.							
7) Claim(s) is/are objected to.								
8) Claims are subject to restriction and/or	election requirement.							
Application Papers								
9) The specification is objected to by the Examiner.								
	10) The drawing(s) filed on is/are objected to by the Examiner.							
11) The proposed drawing correction filed on is: a) approved b) disapproved.								
12) The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. § 119								
13) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	)-(d).						
a) ☐ All b) ☐ Some * c) ☐ None of:	-							
1. Certified copies of the priority documents	have been received.							
2. Certified copies of the priority documents	have been received in Application	on No	- 4					
3. Copies of the certified copies of the priority documents have been received in this National Stage								
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.								
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).								
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Attachment(s)								
5) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449) Paper No(s)  Other:								
2.6.4.4.4.7								

U.S. Patent and Trademark Offic PTO-326 (Rev. 9-00)

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#### **First Office Action on the Merits**

#### Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-49 and the species of compound 113a found in claim 24 in Paper Nos. 6 and 9 are acknowledged. The traversal is on the ground(s) that examination of the subject matter of Groups I-XII would not place a substantially greater burden on the examiner. This is not found persuasive because examination of Groups I-XII in the present application would require a number of various searches and, thus, would place a serious burden on the examiner.

The requirement is still deemed proper and is therefore made **FINAL**.

Note: Upon allowance of generic group of compounds, the various methods of use recited in claims 50-60 reciting compounds of the same scope will be rejoined and allowed in the present application.

2. Based on applicant's election, claims 4, 9-23, 26-48 and 50-60 stand withdrawn from further consideration as being drawn to a nonelected invention.

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### **Duplicate Claims**

3. Claim 6 is objected to under 35 U.S.C. 101 as being a substantial duplicate of claim 1. When one claim is allowed, the other claim will be rejected as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

# Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6-8 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Neef et al. (EP 0,129,499).

Neef et al. teach generic group of 13α-alkyl-gonanes such as 17α-acetoxy-11β-(4-dimethylaminophenyl)-19-norpregna-4,9-dien-3,2 dione (see the entire article, especially examples 1 and 4). The reference teaches the compounds have a strong antigestagenic effect and can be used for postcoital fertility control (see page 2, second paragraph). The compounds and compositions taught by the reference are encompassed by the instant claims.

6. Claims 1-3, 6-8 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al.

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Cook et al. teach 17α-acetoxy-11β-(4-dimethylaminophenyl)-19-norpregna-4,9-dien-3,2-dione (see the entire article, especially examples 1 and 4). The reference teaches the compound have a strong antigestagenic effect (see page 156, compound # 5). The compound and composition taught by the reference are encompassed by the instant claims.

## Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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8. Claims 1-3, 5-8, 24, 25 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. ('886).

Scholz et al. teaches a generic group of 11β-phenyl substituted steroids (see col. 1, line 5 – col. 2, line 53). The reference teaches the compounds and their pharmaceutically compatible addition salts with acids are valuable pharmaceutical agents with antigestagen properties (col. 3, lines 9-13).

The instant claims differ from the reference by reciting compounds not exemplified by the reference, i.e., compounds having a  $17\beta$ -acyl group. However, the reference teaches the  $17\beta$ -position can be substituted with an acyl group that can be further substituted for example with an alkoxy group (see col. 2, lines 20-48).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make any of the species of the reference, including those of the instant claims, with the reasonable expectation that the compound(s) made would have properties as taught by the reference. The motivation is based on the desire to make additional compounds having antigestagen properties as taught by reference.

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9. Claims 1-3, 5-8, 24, 25 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters ('787).

Peeters teaches a generic group of 11β-substituted steroids (see col. 1, line 54 – col. 2, lines 54). The reference teaches the compounds have antiglucocorticoid properties (col. 1, lines 6-9; col. 4, lines 19-39).

The instant claims differ from the reference by reciting compounds not exemplified by the reference, i.e., compounds having a 17β-acyl group. However, the reference teaches the 17β-position can be substituted with an acyl group that can be further substituted for example with an alkoxy group (see col. 2, lines 35-38). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make any of the species of the reference, including those of the instant claims, with the reasonable expectation that the compound(s) made would have properties as taught by the reference. The motivation is based on the desire to make additional compounds having antiglucocorticoid properties as taught by reference.

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### Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Barbara P Badio, Ph.D.

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Primary Examiner Art Unit 1616

BB June 5, 2001

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